

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, and WISCONSIN; the DISTRICT OF COLUMBIA, the CITY OF CHICAGO, and the CITY OF NEW YORK *ex rel.*, and OSWALD BILOTTA,

Plaintiffs,

-against-

NOVARTIS PHARMACEUTICALS
CORPORATION,

Defendant.

11 Civ. 0071 (PGG)

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT NOVARTIS
PHARMACEUTICALS CORPORATION'S MOTION TO EXCLUDE THE
TESTIMONY OF DANIEL L. MCFADDEN**

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Defendant Novartis Pharmaceuticals Corporation (“NPC”) respectfully submits this motion to exclude the expert testimony of Professor Daniel L. McFadden.

PRELIMINARY STATEMENT

The expert reports of Daniel L. McFadden are inadmissible under Federal Rules of Evidence 702 and 403 and Daubert because his opinions are irrelevant and unreliable.

Professor McFadden offers two models in support of his analysis of the effect of purported kickbacks on physicians’ prescription rates: the “Pooled Model” and the “H.B. Model”. Neither can withstand scrutiny.

First, the Government’s purpose in retaining Professor McFadden for this case is to establish that NPC paid kickbacks that “caused doctors to write more prescriptions for Novartis drugs at issue than they otherwise would have”, but Professor McFadden admits that his Pooled Model does no such thing. Rather, the Pooled Model, according to Professor McFadden himself, only measures whether doctors were “at risk” for prescribing additional NPC products, not whether they were actually influenced or caused to do so. Whether doctors were “at risk” of being influenced has no bearing, either legally or factually, on this case and accordingly, the Pooled Model is irrelevant.

Second, both the Pooled Model and the H.B. Model are irrelevant for the separate reason that they do not actually measure whether “kickback” promotional activities—as opposed to other, unchallenged promotional activities—caused doctors to write more prescriptions. The Government has not alleged that certain promotional activities, such as detailing and sampling, are kickbacks, yet Professor McFadden fails to control for the impact of these other promotional activities in his models. As a result, his models cannot measure the impact of the alleged kickbacks on prescribing—rather, they measure only the impact of promotional activities as a whole, including unchallenged legal promotional activities. Without disaggregating the impact

of these confounding factors, Professor McFadden's models do not measure anything of relevance to the case, but rather, simply demonstrate a fact that is already undisputed: promotional programs tend to increase prescriptions (which is exactly what they are designed to do).

Third, failing to adhere to core scientific principles regarding his base assumptions and the need to control for confounding factors not only renders Professor McFadden's opinions irrelevant, but also unreliable.

BACKGROUND

Professor McFadden has been engaged by the Government to provide two opinions: (1) "whether and to what extent Novartis prescription rates among doctors have been influenced by receiving kickbacks"; and (2) the calculation of "damages to the United States and state governments for costs incurred by four health care programs". (McFadden Rep. ¶ 8.) In offering these opinions, Professor McFadden submitted three reports: his opening report ("McFadden Rep."),¹ his supplemental report ("McFadden Supp. Rep.")² and his rebuttal report ("McFadden Rbtl. Rep.")³

In his opening report, Professor McFadden offered only one model, the "Pooled Model", which purportedly calculated the extent to which NPC prescription rates among doctors were influenced by receiving the alleged kickbacks and the resulting damages. Importantly, Professor McFadden's description of what the Pooled Model measures has changed over time.

¹ (Declaration of Benjamin Gruenstein in Support of Novartis Pharmaceuticals Corporation's Motions To Exclude the Proffered Opinions of Plaintiffs' Experts ("Gruenstein Decl."), Exhibit ("Ex.") 3, Expert Report of Daniel McFadden.)

² (Gruenstein Decl. Ex. 4, Supplemental Expert Report of Daniel McFadden.)

³ (Gruenstein Decl. Ex. 5, Rebuttal Expert Report of Daniel McFadden.)

Initially, Professor McFadden claimed that his Pooled Model demonstrated that “[t]he kickbacks identified by [Dr. McMahon’s] criteria⁴ caused doctors to write more prescriptions for Novartis drugs at issue than they otherwise would have”. (McFadden Rep. ¶ 12.) For example, he purported to identify “the number of doctors who were influenced by kickbacks by drug and year” and concluded that “approximately 95 percent of doctors who received kickbacks and were matched to the IMS data would have prescribed fewer new prescriptions but for kickbacks”. (*Id.* ¶ 59.) The reason that such a high percentage of doctors were found to be influenced by Professor McFadden is that his model did not measure the impact of kickbacks on individual doctors but rather on the pool of doctors; in fact, the five percent of doctors that were found not to be influenced included doctors who prescribed only one (or zero) NPC products after attending an event. (Gruenstein Decl. Ex. 6, McFadden Deposition Transcript Excerpts (hereinafter “McFadden Dep. Tr.”) at 121:17-22.)

Upon being challenged by NPC’s damages expert, Dr. Eric Gaier, Professor McFadden admitted that his Pooled Model was not designed to measure the impact of kickbacks on individual doctors. Rather, he clarified that the Pooled Model measured “whether Novartis’s kickbacks increased prescriptions of the drugs at issue overall across the relevant set of kickback-receiving doctors, not whether those doctors were induced to prescribe by kickbacks on a doctor-by-doctor basis”. (McFadden Rbtl. Rep. ¶ 4; see also *id.* ¶ 40 (stating that his Pooled Model “estimates the average kickbacks effect across the population of doctors”).)

Later, at his deposition, Professor McFadden further admitted that not only does the Pooled Model fail to measure the impact of kickbacks on individual doctors, it does not

⁴ Professor McFadden assumed that activities satisfying the criteria identified by other Government experts constitute illegal kickbacks. (McFadden Rep. ¶ 9.) If the court grants NPC’s Daubert motion as to Dr. McMahon, it should also grant this motion as to Professor McFadden.

measure actual impact at all. Instead, the Pooled Model evaluates whether “being exposed to a kickback by the definition [Professor McFadden] was given, increase -- increase the risk that a doctor would write additional prescriptions of the Novartis drugs at issue”. (McFadden Dep. Tr. at 26:15-27:5 (emphasis added).) In other words, Professor McFadden now claims that the Pooled Model evaluates whether doctors who were exposed to purported kickbacks were “at risk” of writing more prescriptions, not that they did so. (Id. at 107:8-108:9 (“Novartis did something improper and that created a risk as judged from the behavior of doctors as a whole, that in a particular following month for that month, that doctor was at risk for doing something improper.” (emphases added)).) However, Professor McFadden acknowledged that a “risk” of prescribing more does not necessarily mean that NPC’s alleged kickbacks actually caused doctors to write more prescriptions. (Id. at 107:8-17 (“Q. You use the phrase ‘an increased risk,’ is that different than saying that the doctor was influenced by the kickback? A. Yes, in the sense that if—the statement if a doctor was influenced by the kickbacks seems to be a statement about the behavior of an individual doctor and the statement about risk is a statement about the behavior of this group of doctors as a class and this is an important logical distinction.”).)

After conceding that the Pooled Model does not measure the impact of alleged kickbacks on individual doctors, Professor McFadden included for the first time in his rebuttal report an entirely new model that purportedly estimates the alleged kickback effect for each doctor: the “Hierarchical Bayes” model (“H.B. Model”). (See McFadden Rbtl. Rep. ¶¶ 39-40.) The H.B. Model is a mix between a model that determines effects on individual doctors and one that applies a population effect. In essence, Professor McFadden claimed that the H.B. Model calculates doctor-specific effects for some doctors and uses those calculations to infer doctor-specific effects for a number of doctors for whom there is “insufficient” data. (See id.)

Neither the Pooled Model nor the H.B. Model controls for the impact of unchallenged legal promotional activities (e.g., detailing and sampling) on prescription rates. Professor McFadden claimed these and other confounding factors need not be controlled for because legal and purportedly illegal “Novartis promotions are a ‘package’”. (Id. ¶ 19.) Specifically, Professor McFadden opined (without citation) that “[d]octors who receive kickbacks are more likely to participate in events—and respond more favorably to—other events, detailing visits, and sampling visits; similarly, doctors who are receptive to these promotions are more likely to receive kickbacks. Therefore controlling for them would artificially reduce the impact of Novartis’s kickbacks demonstrated by the model”. (Id.) Professor McFadden conceded that his “package” theory was not based on his expertise—instead, “it’s based on the logic of how marketing works in general, but not any specific knowledge of pharmaceutical promotions”. (McFadden Dep. Tr. at 164:18-21.)

LEGAL STANDARD

Rule 702 of the Federal Rules of Evidence allows expert testimony only if (1) “the testimony is based on sufficient facts or data”, (2) “the testimony is the product of reliable principles and methods”, and (3) “the expert has reliably applied the principles and methods to the facts of the case”. Fed. R. Evid. 702. Additionally, “the expert’s scientific, technical, or other specialized knowledge” must “assist the trier of fact to understand the evidence or to determine a fact in issue”. Id.; see also Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 591 (1993). “[T]he proponent of expert testimony has the burden of establishing by a preponderance of the evidence that the admissibility requirements of Rule 702 are satisfied.” United States v. Williams, 506 F.3d 151, 160 (2d Cir. 2007); Baker v. Urban Outfitters, Inc., 254 F. Supp. 2d 346, 353 (S.D.N.Y. 2003) (excluding testimony).

In order for expert testimony to be deemed admissible, it must be relevant to an issue the jury will ultimately decide. United States v. Tuzman, 15 Cr. 536 (PGG), 2017 WL 6527261, at *10 (S.D.N.Y. Dec. 18, 2017) (quoting 523 IP LLC v. CureMD.Com, 48 F. Supp. 3d 600, 644 (S.D.N.Y. 2014) (“[A] trial court must consider whether the expert’s testimony will assist the jury. ‘This inquiry looks primarily to whether the testimony is relevant.’”)); see also Fed. R. Evid. 401 (“Evidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action.”).

Expert testimony must also be reliable at every step; “any step that renders the analysis unreliable . . . renders the expert’s testimony inadmissible.” Amorgianos v. Nat’l R.R. Passenger Corp., 303 F.3d 256, 267 (2d Cir. 2002). “[W]hen an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusion reached, Daubert and Rule 702 mandate the exclusion of that unreliable testimony.” Id. at 266.

“[E]ven if the testimony is admissible under Rule 702, it still must pass muster under Rule 403; its probative value must not be substantially outweighed by unfair prejudice.” In re Reserve Fund Secs. & Derivative Litig., No. 09 Civ. 4346 (PGG), 2012 WL 12356742, at *2 (S.D.N.Y. Sept. 10, 2012) (quoting United States v. Dukagjini, 326 F.3d 45, 54 (2d Cir. 2003)).

ARGUMENT

I. PROFESSOR MCFADDEN’S POOLED MODEL SHOULD BE EXCLUDED BECAUSE WHETHER DOCTORS WERE “AT RISK” OF INCREASED PRESCRIBING IS NOT RELEVANT TO AN ISSUE THE JURY MUST DECIDE.

In order for expert testimony to be admissible, it must be relevant to an issue the jury will ultimately decide. Tuzman, 2017 WL 6527261, at *10. Because Professor McFadden’s

Pooled Model measures “risk”—a metric that is irrelevant to the current action—it should be excluded.

In his report, Professor McFadden explained that his assignment was “to address whether and to what extent Novartis prescription rates among doctors have been influenced by receiving kickbacks”. (McFadden Rep. ¶ 8.) But this is not what the Pooled Model does. Instead, as mentioned above, Professor McFadden conceded at his deposition that the Pooled Model identifies doctors “at risk” of writing more NPC prescriptions due to alleged kickbacks. (McFadden Dep. Tr. at 26:15-27:5 (the Pooled Model evaluates whether “being exposed to a kickback by the definition I was given, increase -- increase the risk that a doctor would write additional prescriptions of the Novartis drugs at issue” (emphasis added)).) Being “at risk” of prescribing more does not mean that NPC’s alleged kickbacks actually caused doctors to write more prescriptions:

“Q. You use the phrase ‘an increased risk,’ is that different than saying that the doctor was influenced by the kickback?

A. Yes, in the sense that if – the statement if a doctor was influenced by the kickbacks seems to be a statement about the behavior of an individual doctor and the statement about risk is a statement about the behavior of this group of doctors as a class and this is an important logical distinction.”

(Id. at 107:8-17.) Professor McFadden also testified that it is “perfectly possible” his Pooled Model includes damages for individual doctors who were not actually influenced. (See id. at 135:4-136:12.)

Although the parties dispute whether as a matter of law the Government must establish that doctors in fact increased their prescription writing as a result of receiving kickbacks (see, e.g., Mem. of Law in Opp’n to Def.’s Mot. for Summ. J. and in Supp. of the U.S.A.’s Cross-Mot. for Partial Summ. J. at 37-38, ECF No. 230), neither party contends (nor

would a party be correct in contending) that whether doctors were merely “at risk” for increasing their prescriptions is a fact at issue for determining FCA liability. In fact, the parties agree a relevant inquiry is instead the stated purpose in Professor McFadden’s opening report: “whether and to what extent Novartis prescription rates among doctors have been influenced by receiving kickbacks”. (McFadden Rep. ¶ 8.) Because the Pooled Model is not relevant to determining liability under the applicable legal standard (or even to the stated purpose of Professor McFadden’s report), it is inadmissible and must be excluded under Rule 702 and Daubert.

In addition to being inadmissible under this standard, the Pooled Model should also be excluded under Federal Rule of Evidence 403. Rule 403 provides that “[t]he court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence”. Fed. R. Evid. 403. In fact, “[t]he Second Circuit has noted ‘the uniquely important role that Rule 403 has to play in a district court’s scrutiny of expert testimony, given the unique weight such evidence may have in a jury’s deliberations’.” In re Reserve Fund, 2012 WL 12356742, at *2 (quoting Nimely v. City of New York, 414 F.3d 381, 397 (2d Cir. 2005)).

As explained above, the Pooled Model’s “at risk” analysis is separate from and not relevant to the issue of whether kickbacks induced doctors to write NPC prescriptions. Therefore Professor McFadden’s opinion confuses the issues and is highly likely to mislead the jury into thinking that causation is established if a doctor is at increased risk. Indeed, his report itself contains many misleading declarative statements about causation, although Professor McFadden admitted at deposition that he established no such thing. For example, the jury is likely to be confused or misled by Professor McFadden’s opinion that “approximately 95 percent

of doctors who received kickbacks and were matched to the IMS data would have prescribed fewer new prescriptions but for kickbacks” (see McFadden Rep. ¶ 59) when, according to Professor McFadden’s testimony elicited at deposition, the Pooled Model only addresses whether “there is a risk that a doctor in this circumstance would increase prescriptions” (McFadden Dep. Tr. at 52:9-14). Similarly, the jury is likely to be misled by Professor McFadden’s opinion that “[t]he kickbacks identified by the criteria caused doctors to write more prescriptions for Novartis drugs at issue than they otherwise would have” (McFadden Rep. ¶ 12), when in fact the Pooled Model was “[not] intended to show . . . the behavior of a particular doctor” (McFadden Dep. Tr. at 55:9-16).

Although it appears that the Government first intended for Professor McFadden to opine on the impact of alleged kickbacks on prescription rates, over time it has become clear that Professor McFadden is instead opining on the number of physicians “at risk” of increasing prescribing in response to alleged kickbacks. This is an unclear opinion, the irrelevance of which is further underscored by his opinion that almost all of the doctors—indeed, 95 percent of them—are “at risk” of being influenced, and the only doctors who are not at risk are those that prescribed only one (or zero) prescriptions following a purported kickback event. The jury will not draw anything of probative value from this testimony.

II. NEITHER THE POOLED MODEL NOR THE H.B. MODEL IS RELEVANT TO DETERMINING WHETHER ILLEGAL KICKBACKS CAUSED AN INCREASE IN PRESCRIPTIONS BECAUSE NEITHER CONTROLS FOR CONFOUNDING FACTORS.

It is well-settled that expert-offered regression models must account for potential confounding factors. See Reed Constr. Data Inc. v. McGraw-Hill Cos., Inc., 49 F. Supp. 3d 385, 396-97 (S.D.N.Y. 2014) (explaining the basic regression method and purpose of controlling for confounding variables). “Confounding occurs when another causal factor (the confounder)

confuses the relationship between the agent of interest and the outcome of interest.” Michael D. Green, Michal Freedman & Leon Gordis, Reference Guide on Epidemiology, in Reference Manual on Scientific Evidence 549, 591 (3d ed. 2011), available at <https://www.fjc.gov/sites/default/files/2015/SciMan3D01.pdf>.⁵

Professor McFadden himself agrees that a proper model must account for confounding factors. (See, e.g., McFadden Dep. Tr. at 27:10-12 (“I designed a model which is – which tries to control for factors that would confound a finding of causality.”).) He also testified that if confounding factors are not accounted for, his models could mistake mere correlation for causation:

“Q. And if there’s merely correlation, but not causation, would that be detected by your model? [objection]

A. I – I think the – to phrase the question in econometric, correct, econometric way, what you would say is if there are other causal factors, have they not been accounted for in this model so that the correlation you see is due to something other than the causation. I think that is how far econometrics can go.

Q. So if there are other causal factors that have not been identified and accounted for, it’s possible that the results of your model can simply reflect correlation as opposed to causation? [objection]

A. I would say within the framework of econometric modeling, the hypothetical you state is possible.”

(Id. at 30:6-31:2.)

All promotional activities, including detailing and sampling, can have a positive impact on prescription rates. (See Gruenstein Decl. Ex. 15, Expert Report of Eric M. Gaier, at 10 n.33, 32 n.144 (citing Gruenstein Decl. Ex. 16, Sridhar Narayanan and Puneet Manchanda,

⁵ Courts frequently rely on the Reference Manual on Scientific Evidence. See, e.g., Amorgianos, 303 F.3d at 265; In re Rezulin Prods. Liab. Litig., 369 F. Supp. 2d 398, 406-07 nn.55-61 (S.D.N.Y. 2005).

“Heterogeneous Learning and the Targeting of Marketing Communication for New Products,” Marketing Science: Vol. 28, No. 3 (2009), at 425, 432)); c.f. Sorrell v. IMS Health, Inc., 564 U.S. 552, 557-58 (2011) (explaining the legal, promotional process of detailing to “persuade [doctors] to prescribe a particular pharmaceutical”). It is undisputed that increasing prescriptions is a proper purpose of legal marketing practices. It is also undisputed that the Government has not alleged that NPC’s detailing and sampling practices were unlawful.

Despite the fact that the impact of detailing and sampling on prescription rates is not at issue, Professor McFadden did not control for these confounding factors in either his Pooled or H.B. Models.⁶ (See, e.g., McFadden Dep. Tr. at 95:10-96:3; McFadden Rbtl. Rep. ¶¶ 16-19.) Notably, Professor McFadden does not, and cannot, dispute that unchallenged promotional practices such as detailing and sampling can positively impact prescription rates. (See McFadden Rbtl. Rep. ¶ 19.) Rather, for the first time in his rebuttal report, Professor McFadden asserted that he need not control for these practices in his models because they are part of a “package” of NPC promotional activities that includes providing kickbacks. (See id.) Specifically, Professor McFadden claimed that “[d]octors who receive kickbacks are more likely to participate in events – and respond more favorably to – other events, detailing visits, and sampling visits; similarly, doctors who are receptive to these promotions are more likely to receive kickbacks. Therefore controlling for them would artificially reduce the impact of

⁶ Professor McFadden also fails to control for the impact of unchallenged speaker and roundtable events. Importantly, the Government’s theory of liability in this case attaches only after a third event is attended within a particular period, leaving the first two events attended within that period unchallenged. (See McFadden Rep. ¶ 10.) Yet Professor McFadden opines that although “first or second events for a particular drug attended in a six-month period are not identified as kickback events[, they] are part of a kickback pattern and should not be assumed to be legitimate”. (See McFadden Rbtl. Rep. ¶ 14.) Professor McFadden has no basis for this assumption. Because the Government does not allege that first or second events are illegitimate, the impact of unchallenged first and second events on prescribing after the third event is a confounding factor for which Professor McFadden must control.

Novartis's kickbacks demonstrated by the model". (Id.) However, Professor McFadden has no basis for this assertion.

Professor McFadden is not designated as an expert in marketing or in medicine.

In fact, in his deposition, Professor McFadden explained that the assumptions underlying his "package theory" were not based on his expertise at all:

"Q. What is the basis for your opinion that doctors who receive kickbacks are more likely to participate in other non-kickback events, detailing visits and sampling visits?

A. The sentence is declarative but the intention was to indicate that this was possible and a concern that you would have to consider.

Q. So just to be clear, you're not saying this as a fact, you're saying it as a possible fact? [Objection].

A. Yes, a better language are – change are to –

Q. Could be?

A. Could be, yes.

Q. And you also say with the change in language, 'doctors who receive kickbacks could be more likely to respond more favorably to other events, detailing visits and sampling visits'; did I rephrase it to capture your meaning?

A. I accept that.

Q. Okay. You also then say 'Similarly, doctors who are receptive to these promotions are more likely to receive kickbacks'; could I change that to be could be as well?

A. Could be, maybe.

Q. So the first question is, is this your speculation or is it based on anything that you know about pharmaceutical promotion?

A. It's – it's based on the logic of how marketing works in general, but not any specific knowledge of pharmaceutical promotions."

(McFadden Dep. Tr. at 163:10-164:21) (emphases added). Professor McFadden further testified that he did not perform any research on detailing or sampling (id. at 13:19-24), that he is not aware of the academic literature discussing the impact that detailing can have on prescribing (id. at 96:11-16), and that competitor programming—as opposed to NPC programming—could also have a positive impact on the prescription rate of NPC drugs (id. at 195:2-197:2).

Moreover, Professor McFadden conceded that it may be possible to control for confounding factors such as these, but that he did not do so:

“Q. You don’t think there’s a way to untangle the impact of detailing say from speaker programs?

A. I’ll answer the question at two levels. One, I wouldn’t rule it out that there’s a way to do it . . . I would have to become much more expert in pharmaceutical [] marketing than I am, which I am not currently.”

(Id. at 156:21-157:15. See also id. at 157:5-158:6 (“So I can say as a general matter, control variates approach would be the way I would start thinking about it, but I don’t know what the outside variables needed to implement that would be.”).) Therefore, Professor McFadden’s “package” theory, which lies on unfounded assumptions outside of his area of expertise, is improper testimony for an expert and cannot save his opinion. See Reed Constr. Data Inc., 49 F. Supp. 3d at 406 (“The issue with [the expert’s] two responses is that they do not rest on qualities of his expertise. [The expert] is, by training, an economist and an econometrician. He is qualified to opine only on areas within the scope of those fields.”).

Professor McFadden’s failure to control for the impact of unchallenged promotional practices is a critical error.⁷ Without controlling for practices like detailing and

⁷ In addition to rendering his opinions irrelevant, Professor McFadden’s failure to account for significant confounding factors also renders his models unreliable and is therefore separate grounds for exclusion under Rule 702 and Daubert. See Reed Constr. Data Inc., 49 F. Supp. 3d at 400 (“[T]o be admissible, a regression analysis must control for the ‘major factors’ that might

sampling, Professor McFadden’s models merely address whether promotional activities as a whole increase prescription writing—something that is not an issue in this case.⁸

Federal Rule of Evidence 403 also weighs in favor of excluding both the Pooled and H.B. Models. The relevant inquiry in this case, and the topic on which Professor McFadden was retained to opine, is whether NPC’s alleged violation of the AKS caused doctors to write additional prescriptions. By failing to control for confounding factors, the Pooled Model and H.B. Model only show that promotional activity generally—including promotional activity that is not violative of the AKS—increased prescriptions, which is an irrelevant inquiry. Permitting the jury to consider these models would be misleading and confusing and would waste time, especially given the additional questions and explanations that would be necessary to explain and rebut Professor McFadden’s methodology and also to explain the meaning and importance of confounding factors within regression models.

influence the dependent variable.”), aff’d, 638 F. App’x 43 (2d Cir. 2016). Moreover, “it is the ‘proponent [of the testimony] who must establish that the major factors have been accounted for’.” Id. at 403 (quoting Freeland v. AT&T Corp., 238 F.R.D. 130, 145 (S.D.N.Y. 2006)).

⁸ In his rebuttal report, Professor McFadden included a single paragraph with a revised damages calculation for his Pooled Model that purports to take into account these confounding factors. (See McFadden Rbtl. Rep. ¶ 28.) Professor McFadden does not explain the methodology he used to control for these factors. (See McFadden Dep. Tr. at 156:21-157:15.) Moreover, for the reasons explained in Section I supra, Professor McFadden’s Pooled Model is irrelevant because it only identifies doctors who were “at risk” of prescribing more as a result of the alleged kickbacks. Professor McFadden provides no similarly revised damages calculation for his H.B. Model.

CONCLUSION

For the foregoing reasons, the Court should exclude Professor McFadden's proffered opinions on whether and to what extent NPC prescription rates among doctors have been influenced by receiving alleged kickbacks.

Dated: September 28, 2018

Respectfully submitted,

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